OCT 3 0 2003

510(K) SUMMARY

DIO-DENT 10 DENTAL DIODE LASER SYSTEM

510(k) Number K 031819

Applicant's Name: MSq(M^2) Ltd.
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Push-med Ltd.
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Date Prepared: May 2003

Trade Name: Dio-Dent 10 Dental Diode Laser System

Classification Name: Laser Instrument, Surgical, Powered

Classification: FDA has classified laser device as a class II device (product code GEX) and it is reviewed by the General & Plastic Surgery Panel.

Predicate Devices: The Dio-Dent 10 Dental Diode Laser System substantially equivalent to the Ceralase D 980nm Diode Laser System, Model D15 (Ceramoptec, Inc.) cleared under K983058, K991891, K993002, K993911 and K022351 in terms of technological characteristics, performance, intended use, indications for use and user interface.

In addition, the Dio-Dent 10 is substantially equivalent to the Opus 10 Dental Diode Laser System (OpusDent Ltd.) cleared under K000990 and K011769 in terms of intended use, indication for use, technological characteristics, performance and user interface.

Performance Standards: The Dio-Dent 10 Diode Laser complies with:

U.S. Federal Performance Standards 21 CFR 1040.10 and 21 CFR 1040.11 for class IV Laser Products.

In addition, the device complies with the European Medical Directive 93/42/EEC concerning medical devices (Annex II) and with the voluntary standards IEC 60601-1, IEC 60601-1-2, IEC-60825-1 and IEC 601-2-22.

Intended Use / Indication for Use: The Dio-Dent 10 Dental Diode Laser System is intended for incision, excision, ablation, vaporization and/or coagulation (hemostasis) of oral soft tissue (including marginal and interdental gingiva and epithelial lining of free gingiva). In addition, the system is intended for teeth whitening.

The Indications for Use of the Dio-Dent 10 Dental Diode Laser System include:

Cosmetic Dentistry
- Light activation for bleaching materials for teeth whitening
- Laser-assisted bleaching/whitening of the teeth

Endodontology
- Pulpotomy
- Pulpotomy as an adjunct to root canal therapy

Periodontology
- Sulcular debridement (removal of diseased or inflamed soft tissue in the periodental pocket)

Oral Soft Tissue Surgery
- Biopsy
- Operculectomy
- Gingivectomy
- Gingivoplasty
- Oral papillectomy
- Leukoplakia
- Treatment of aphthous ulcers
- Fibroma removal
- Frenectomy
- Frenotomy
- Tissue retraction for impressions
- Incising and draining of abscesses
- Draining fistulas
- Exposure of unerupted partially erupted teeth
- Lesion (tumor) removal
- Implant recovery

- Implant uncovering
- Gingival troughing
- Crown lengthening
- Hemostasis of donor site
- Coagulation and decontamination of extraction sites
- Removal of granulation tissue
- Degranulation of infrabony defects
- Laser assisted flap surgery
- Vestibuloplasty
- Removal of hyperplastic tissues
- Debridement of diseased epithelial lining

Device Description: The Dio-Dent 10 Dental Diode Laser is designed to perform several medical procedures in the oral soft tissue and to perform laser assisted aesthetic tooth whitening procedures.
A Gallium Aluminum Arsenide (GaAlAs) solid state laser diode provides optical energy to oral soft tissues.
A fiber optic held by a handpiece delivers up to 10Watts laser energy. A visible light emitted from the handpiece's distal end targets the area of treatment. The optical power output and pulse may be adjusted to specific use requirements.

Substantial Equivalence: There are no unique applications, indications, material or specifications presented below. Evidence of equivalence has been demonstrated through:

- The Dio-Dent 10 intended use and indications for use were previously cleared by FDA for the predicate devices.
- The technical characteristics of the Dio-Dent 10 are similar to those of the cleared Ceralas™ and Opus 10™.
- Laser output values of the Dio-Dent 10 are well within previous cleared values of the predicate dental diode laser systems as described.
- The predicate devices and other previous cleared lasers with similar energy output have a proven safety and effectiveness in the treatment of the claimed indications.
- Safety and performance testing.

Therefore. the Dio-Dent 10 Dental Diode Laser System is substantially equivalent to its predicate devices cited above and raises no new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 3 0 2003

MSq(M^2) Ltd.
c/o Mr. Arava Hacohen
Push-med Ltd.
117 Ahuzah Street
Ra'anana 43373, Israel

Re: K031819
Trade/Device Name: Dio-Dent 10 Dental Diode Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: June 1, 2003
Received: July 30, 2003

Dear Mr. Hacohen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K 031819

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(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

510(k) Number K031819

Prescription Use ✓
(Per 21 CFR 801.109)

OR Over the Counter Use ____

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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